



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 24, 2000

Thomas O. Henteleff
Stacy L. Ehrlich
Kleinfeld, Kaplan & Becker
1140 Nineteenth Street N.W.
Washington, DC 20036-6601

Dear Sirs:

Your petition submitted on behalf of Braintree Laboratories, Incorporated requesting the Food and Drug Administration to reclassify the over-the-counter sodium phosphate bowel preparation products and to require a boxed warning on the labeling for safety concerns was received by this office on 08/23/00. It was assigned docket number 00P-1472/CP 1 and it was filed on 08/23/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

00P-1472

ACK1